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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/691,119

10/21/2003

Kirk Patrick Seward

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02/26/2009

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EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

02/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|----------------------|---------------|--|
| <i>Office Action Summary</i> | Application No. | Applicant(s) | |
| | 10/691,119 | SEWARD ET AL. | |
| | Examiner | Art Unit | |
| | CATHERINE N. WITCZAK | 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-23 and 30-44 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 and 42-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 18 and 30-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 17, 30-41 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Beyerlein (US 2003/0120297).

Beyerlein discloses in Figure 2 a method for injecting a pharmaceutical agent beyond the EEL of a coronary blood vessel by 5mm or less and confirming the position of the needle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beyerlein as modified by Greff (US 2005/0090714)

Beyerlein discloses the claimed invention except for the step of confirming the position of the needle by injecting contrast media through the needle aperture and observing distribution of the media. Greff discloses in Figure 1 and paragraph [0076] that it is known to confirm the

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position of a needle tip by injection contrast media and observing its distribution. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Beyerlein with the step of confirming the location of the needle tip as taught by Greff, since such a modification would allow for another accurate placement method for determining the location of the needle tip in the method of Beyerlein.

Response to Arguments

Applicant's arguments filed 12/17/2008 have been fully considered but they are not persuasive. Applicant argues that because the distance between the luminal wall and the EEL may vary, the needle of Beyerlein's device may extend into regions where it is not intended to be placed. Applicant thus argues that Beyerlein does not teach the step of confirming the position of the needle aperture before injecting a pharmaceutical agent. Examiner disagrees. Although Beyerlein's method of confirming that a delivery aperture of a needle has penetrated past the EEL is not be consistently effective (for reasons such as those pointed out by the Applicant) – this does not mean that Beyerlein does not disclose the step of confirming that the needle has penetrated past the EEL. Beyerlein teaches a method of providing contact and penetration depth sensing for localized, periadvential delivery of a treatment agent (paragraphs [0018 and 0028]). Since Beyerlein teaches a method of localized delivery and also discloses the idea of ascertaining the delivery being administered to the correct location, it would be obvious to one of ordinary skill in the art to modify the method with a more precise confirmation of needle aperture placement as taught by Greff. Greff teaches the use of injecting contrast agent to determine in the agent is being delivered to the intended delivery site (paragraph [0028]). Therefore, since Greff, teaches a more reliable method of performing Beyerlein's step of confirming the injection location it would have been obvious to modify Beyerlein's method with the teaching of Greff.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Catherine N Witczak/

Examiner, Art Unit 3767

/Kevin C. Simons/

Supervisory Patent Examiner, Art Unit 3767